

THAT WHICH IS CLAIMED IS:

1. A method of administering a thermal therapy to treat a condition of the prostate using a closed loop thermal treatment system, comprising:

inserting a treatment catheter having a liquid circulation path and an expandable treatment balloon in fluid communication therewith into the male urethra of a subject such that the treatment balloon is positioned in the lumen of the prostatic urethra, the prostatic urethra lumen having a wall and a cross-sectional width, and wherein the treatment catheter defines a portion of a closed loop thermal treatment system;

expanding the treatment balloon outwardly a distance to cause the treatment balloon to contact the wall of the prostatic urethra and exert pressure onto tissue proximate the prostatic urethra;

substantially continuously circulating heated liquid through the liquid circulation path and the expanded treatment balloon for a time of at least 15 minutes to heat tissue surrounding the prostatic urethra;

monitoring the pressure in the closed loop system; and
automatically adjusting the pressure in the closed loop system based on the pressure determined by the monitoring step to compensate for operational pressure losses in the closed loop system and physiological changes in the tissue proximate the targeted treatment region in the prostatic urethra so that the system maintains at least one selected operating pressure during administration of the thermal therapy.

2. A method according to Claim 1, wherein the circulating liquid step comprises heating the circulating liquid to a first temperature during a first portion of the thermal therapy

and then heating the circulating liquid to a second, higher temperature during a second portion of the thermal therapy, and wherein the pressure adjusting step is carried out so that the system maintains a substantially constant pressure of between about 0.5 to 3 atm during the second portion of the 30 thermal therapy.

5 3. A method according to Claim 2, wherein the step of adjusting the pressure is carried out so that it maintains a substantially constant system pressure of between about 1-3 atm for the second portion of the administration of the thermal therapy, the second portion of the therapy starting about five-ten minutes from the beginning of the treatment.

10 4. A method according to Claim 1, wherein the cross-sectional width of the lumen of the prostatic urethra increases based on the steps of expanding, circulating liquid, and adjusting the pressure.

5 5. A method according to Claim 1, wherein the administered thermal therapy is a thermal ablation therapy, and wherein the circulating liquid step comprises circulating liquid heated to between about 45°-95°C for at least about 5-10 minutes.

15 6. A method according to Claim 5, wherein the steps of circulating liquid and adjusting the pressure are carried out such that the closed loop system has a first system pressure and the circulating liquid has a corresponding first heated temperature, and further has a second system pressure with the circulating liquid having a corresponding second heated temperature, the second temperature being generated after about at least five minutes from when the first temperature is
20 generated, wherein the second temperature is greater than the first temperature.

7. A method according to Claim 1, wherein the pressure in the system is carried out such that it is substantially constant for a major portion of the duration of the administered

thermal therapy.

8. A method according to Claim 6, wherein the first temperature is about 45 to 50°C and the second temperature is between about 57° to 95°C, and wherein the second system pressure is controlled such that it is substantially constant or increases relative to the first system
5 pressure for a time of at least about 5-20 minutes.

9. A method according to Claim 5, wherein the steps of expanding, circulating the liquid, and adjusting the pressure are carried out to provide an increased thermal ablation treatment depth sufficient to cause tissue necrosis at a penetration depth of at least about 15 mm on average measured about the lumen 5 the prostatic urethra.

10 10. A method according to Claim 9, wherein the steps of expanding, heating, and adjusting are carried out at times and pressures sufficient to generate a crust about the wall of the lumen of the prostatic urethra, the crust having a sufficient thickness to define a natural stent that can maintain an open passage through the prostatic urethra post-treatment.

11. A method according to Claim 1, wherein the liquid circulation path is between
15 about 10 to 20 feet long.

12. A method according to Claim 11, wherein the liquid circulation path comprises lengths of interconnected elastomeric tubing with a plurality of connection joints, the tubing being in fluid communication with the treatment catheter.

13. A method according to Claim 1, wherein the steps of monitoring and adjusting the
20 pressure are repeated over a plurality of patients having different physiologic prostate densities and using different treatment catheters or different lengths of treatment balloons, and wherein the steps of monitoring and adjusting the pressure are carried out to provide substantially constant

system pressures for corresponding portions of the thermal therapies between patients, thereby providing improved consistency of treatment from one patient to another patient.

14. A method according to Claim 1, wherein the initial quantity of liquid circulating in the closed loop system is less than 100 ml, and wherein the step of adjusting the pressure

5 comprises introducing additional quantities of liquid therein.

15. A method according to Claim 14, wherein the circulation path comprises a resilient portion, and wherein the adjusting step comprises compressing the resilient portion to increase the pressure in the closed loop system.

16. A method according to Claim 15, wherein the resilient portion is a compressible

10 bag positioned intermediate two substantially rigid members, and wherein the step of adjusting the pressure is carried out by forcing the two rigid members toward one another.

17. A method according to Claim 15, wherein the resilient portion is held in a rigid housing and the adjusting step is carried out by introducing gas into the housing to compress the resilient portion to increase the pressure.

15 18. A method according to Claim 15, wherein the resilient portion is an bellows member which is axially extendable and compressible to greater and lesser axial lengths, and wherein the adjusting step comprises compressing the bellows member to take on a shorter length to increase the pressure in the closed loop system.

19. A method according to Claim 1, further comprising accepting user input to set the

20 operating system pressure, constrained by predetermined pressure limits, during at least a portion of the administration of the thermal therapy.

20. A method according to Claim 1, wherein the step of adjusting the pressure is carried

out by a pressure adjustment device located in-line with the liquid circulation path.

21. A method according to Claim 1, wherein the step of adjusting is carried out by a pressure adjustment device located offset to a portion of the liquid circulation path.

22. A method according to Claim 1, wherein the thermal therapy is administered to
5 treat prostatitis.

23. A method according to Claim 5, wherein the thermal therapy is administered to treat BPH.

24. A closed loop thermal treatment system, comprising:

a treatment catheter having a circulating liquid inlet channel and a circulating liquid
10 outlet channel, and an expandable treatment balloon in fluid communication with the circulating inlet and outlet channels;

a pump operably associated with the treatment catheter;

a heater operably associated with the treatment catheter;

at least one temperature sensor operably associated with the treatment catheter and the

15 heater;

a pressure sensor operably associated with the treatment catheter;

a pressure adjustment device operably associated with the pressure sensor and the
treatment catheter;

a closed loop liquid circulation path adapted to circulate a quantity of liquid therein, the
20 path including the treatment catheter inlet and outlet channels and the treatment balloon, wherein
the pressure adjustment device is operably associated with the liquid circulation path; and

a controller operably associated with the pump, heater, temperature sensor, pressure

sensor, and pressure adjustment device, the controller having computer program code for:

(a) activating the pump, the heater, the temperature sensor, the pressure sensor and the pressure adjustment device to substantially continuously circulate heated liquid through the liquid circulation path; and

5 (b) automatically adjusting the pressure in the liquid circulation path to compensate for operational pressure losses over a time of at least about 15 minutes in the treatment system and to account for physiological changes in the tissue proximate the targeted treatment region in the prostatic urethra so that the system maintains at least one selected operating pressure during administration of the thermal therapy.

10 25. A system according to Claim 24, wherein the computer code further comprises code for adjusting the operational pressure in the liquid circulating system to predetermined constant or increasing pressures.

26. A system according to Claim 24, wherein the computer code further comprises code for adjusting the temperature and for directing the pressure in the liquid circulation path to increase so that it has an increased pressure in a later portion of the treatment over that in the first 15 5-10 minutes of the treatment.

27. A system according to Claim 24, wherein the computer code further comprises code for directing the pressure in the liquid circulation path to remain substantially constant over a major portion of the treatment.

20 28. A system according to Claim 24, wherein the pressure adjustment device comprises a resilient member with a substantially centrally located aperture extending therethrough and opposing rigid members with a threaded coupling member extending therebetween through the

aperture of the resilient member, wherein, in operation, the rigid members cooperate to compress the resilient member and increase the pressure in the liquid circulation path and in the treatment balloon.

29. A system according to Claim 24, wherein the pressure adjustment device comprises
5 a resilient member encased in a housing having a fluid port, and a fluid source in fluid communication with the fluid port, and wherein, in operation, fluid is directed into the fluid port to compress the resilient member to increase the pressure.

30. A method of treating BPH using a closed loop thermal treatment system,
comprising:

10 inserting a treatment catheter having a liquid circulation path and an expandable treatment balloon in fluid communication therewith into the male urethra of a subject such that the treatment balloon is positioned in the lumen of the prostatic urethra, the prostatic urethra lumen having a wall and a cross-sectional width, and wherein the treatment catheter defines a portion of a closed loop thermal treatment system;

15 expanding the treatment balloon outwardly a distance to cause the treatment balloon to contact the wall of the prostatic urethra and exert pressure onto tissue proximate the prostatic urethra;

substantially continuously circulating liquid heated to between about 57° to 95°C through the liquid circulation path and the expanded treatment balloon for a time of at least about 5
20 minutes to heat tissue surrounding the prostatic urethra so to that a thermal ablation therapy is administered thereto;

monitoring the pressure in the closed loop system;

automatically adjusting the pressure in the closed loop system based on the pressure determined by the monitoring step to compensate for operational pressure losses in the closed loop system and physiological changes in the tissue proximate the targeted treatment region in the prostatic urethra so that the system maintains at least one selected operating pressure during

5 administration of the thermal therapy; and

increasing the width of the lumen of the prostatic urethra based on the expanding, circulating liquid, and pressure adjusting steps.

31. A method according to Claim 30, wherein the heating step comprises heating the circulating liquid to a first temperature of between about 45-55°C during a corresponding first portion of the thermal therapy and then heating the circulating liquid to a second temperature between about 57°-95°C during a corresponding second portion of the thermal therapy, and wherein the step of adjusting the pressure is carried out so that the system maintains a substantially constant pressure of between about 0.75-3 atm during the second portion of the thermal therapy.

15 32. A method according to Claim 31, wherein the step of adjusting the pressure is carried out so that it maintains a substantially constant system pressure of at least about 1.0-2 atm during the second portion of the thermal therapy, the second portion of the therapy starting about five-ten minutes from the initiation of the treatment.

33. A method according to Claim 30, wherein the steps of expanding, circulating liquid, and adjusting are carried out to provide an increased thermal ablation treatment depth sufficient to cause tissue necrosis at a penetration depth of at least about 15-20 mm on average measured about the lumen of the prostatic urethra.

34. A method according to Claim 30, wherein the steps of expanding, circulating liquid, and adjusting the pressure are carried out with sufficient heat and pressure to generate a crest about the wall of the lumen of the prostatic urethra having a sufficient thickness to define a natural stent that can maintain an open passage through the prostatic urethra post-treatment.

5 35. A method according to Claim 30, wherein the liquid circulation path is about 10-20 feet long.

36. A method according to Claim 30, further comprising insulating a portion of the liquid circulation path to inhibit undue heating of non-targeted tissue.

37. A method according to Claim 30, further comprising insulating non-targeted tissue
10 below the targeted region such that the non-targeted tissue is exposed to a maximum temperature of about 44°C from contact with the treatment catheter during the step of circulating liquid.

38. A method according to Claim 37, further comprising directing body fluids to drain through the treatment catheter during the step of circulating liquid.

39. A method of treating BPH, comprising:
15 contacting tissue in the prostatic urethra with a heated fluid filled expanded treatment balloon; and

circulating fluid to concurrently conductively heat and exert pressure onto the prostatic urethra with sufficient force and temperature to thermally ablate tissue in the prostatic urethra to cause tissue necrosis to a penetration depth of at least about 15-20 mm on average when
20 measured about the circumference of the prostatic urethra lumen.

40. A method according to Claim 39, further comprising generating a crest about the wall of the lumen of the prostatic urethra, the crest having a sufficient thickness to define a

natural stent that can maintain an open passage through the prostatic urethra post-treatment.

41. A method of thermally treating a target region in the body of a subject using a thermal treatment system with a closed loop circulation path, comprising:

- (a) inserting a treatment catheter into a body lumen of the subject;
- 5 (b) heating liquid external of the subject to above about 40°C;
- (c) circulating the heated liquid in a closed loop circulation path including a treatment catheter having an expandable treatment balloon;
- (d) exposing tissue in a targeted region of the subject to a temperature of above about 40°C for a predetermined thermal ablation treatment period by heating the tissue based at least in
- 10 part on the circulating step;
- (e) insulating non-targeted tissue below the targeted region such that the non-targeted tissue is exposed to a maximum temperature of about 44°C from contact with the treatment catheter during the circulating step;
- (f) monitoring the pressure in the system; and
- 15 (g) automatically adjusting the pressure in the closed loop circulation path to compensate for physiologic changes in the tissue in the targeted region of the subject and pressure decreases over a period of at least about 15 minutes.

42. A method according to Claim 41, wherein the step of adjusting the pressure is carried out by removing from or adding to the amount of liquid in the circulation path based on

20 the monitoring step.

43. A method according to Claim 42, further comprising directing body fluids to drain through the treatment catheter during the circulating step.